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October 11, 2000

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

Docket Number 92N-0297

Dear Sir or Madam:

The Food Marketing Institute (FMI) respectfully requests an opportunity to testify at the Food and Drug Administration's (FDA) public hearing that will be held on October 27, 2000, on issues relating to regulations implementing the Prescription Drug Marketing Act (PDMA).

By way of background, FMI i9s a non-profit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customer, in the Untied States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with combined annual sales volume of \$220 billion, which accounts for more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Our international membership includes 200 members from 60 countries.

Within FMI's retail membership ranks, we have some 123 companies that are presently operating 7,700 in-store pharmacy departments. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years. Because of the growing prominence of pharmacies in the supermarket industry, and in recognition of the fact that with few exceptions, our members routinely purchase prescription drugs from secondary wholesalers, FMI has an overriding interest in FDA's regulations implementing certain PDMA provisions.

If granted an opportunity to testify, FMI would limit our oral presentation to approximately ten minutes. It is our intention to respond to the six questions that FDA has expressed a specific interest. FMI's statement would also address issues relating to



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YOUR NEIGHBORHOOD SUPERMARKETS

PDMA as enacted into law by the Congress. We are planning to have Ty Kelley, FMI's Director of Government Relations, present our industry statement. His direct phone number is 202/220-0629.

In closing, we hope that FDA will grant our request to participate in the agency's public hearing regarding regulations implementing the PDMA.

Sincerely,

John J. Motley III Senior Vice President

Government and Public Affairs